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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,997

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Peiyuan Wang

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08/02/2010

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EXAMINER

PACKARD, BENJAMIN J

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

08/02/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/632,997	Applicant(s) WANG ET AL.	
	Examiner Benjamin Packard	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 19, 26, 28, 29, 31 and 33-37 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 is/are allowed.
- 6) ☒ Claim(s) 18, 21-24, 27, 30 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1pg (5/20/10)</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 5/20/10, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Election/Restrictions

Applicants request that clarification is made that the newly elected species was 1(O), as stated in the Response filed Aug 21, 2009. Applicants also request that the election be reconsidered where the claims are directed to a limited number of species which share a common utility.

Examiner acknowledges this election and notes the rejections sent out were directed to the compound of 1(O), as evidenced by the rejection at pg 4 of the Office Action mailed 11/23/09. The note of 1(T) on pg 2 of the Office Action appears to have simply been a typographical error.

Examiner disagrees with the reasons to reconsider the restriction. First, Examiner notes the election was made final in the last action.

Second, even if Examiner were to reconsider, generic claim 18 is directed to a genus of bicyclo-compounds where the number of core ring varies in the number of heteroatoms, resulting in different class/subclass designations. Additionally, the presence of additional ring systems fused the bicyclic core also varies the compounds,

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resulting in a large number of potential compounds and class/subclasses. Thus, the “liberal” application of a “reasonable” number of compounds would still not be satisfied by the instant claims.

Examiner notes Applicants are correct in their response to the obviousness rejection that claim 13 recites a proviso that when W is O, R4' and R5' are hydroxyls, and R4 and R5 are hydrogen that a 8-azaxanthinyl ring is not formed. As such, claim 13, 14 and 25 should have been withdrawn as being directed to non-elected species in the last Office Action due to an error. As such, claims 13, 14, and 25 are now withdrawn as being directed to non-elected species.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18, 21-22, 27, 30, 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al (J. Org. Chem., 1976, 41 (7), 1100-1104) in view of Patani et al (Chem. Rev. 1996, 96, 3147-3176).

Applicants assert there is no reason to select the compound of Sasaki et al as a lead compound, no reason to modify that exact compound, or that one making such modifications would succeed in that modification. Specifically, Applicants assert case law requires the recognition of a “lead compound” and motivation to select the same compound as the lead. Further, Applicants assert Patani et al is directed to explaining specific instances of bioisosterism and not providing motivation for chemical

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modification. Applicant then assert Patani suggests only modification of lead compounds and that the skilled artisan would not pick the specific modification of replacing -C=O- with -N=H- to get the present compound. Applicants also assert the compounds 1(A), 1(C), and 1(D) of claim 18 differ from the compound of Sasaki because they contain different and/or only one heteroatom

Examiner disagrees. First, while Sasaki et al discloses a specific structural compound as compound 4 and while suggesting there may be an alternative structural form due to irregular resonances of compound 4, the structures of 3 and 4 were firmly established by the thermal conversion of 6 into 3a (Sasaki et al, pg 1101 right column about lines 30-34). As such, compound 4 would be the end product and would reasonably be considered a lead, along with the related compound 3. As the lead compounds, there would be an expectation that the compound would be among the compounds which show biological activity, or at least provide motivation to the skilled artisan to test the compounds for biological activity with an expectation of success where some compounds which are structurally similar have been of biological interest.

Second, Patani et al explains specific instances of bioisosterism, but the skilled artisan would not read such a disclosure to be limited to only those disclosed embodiments. Instead, the skilled artisan would understand the concept of the paper is to provide an outline of common uses of bioisosterism in modification of lead compounds into safer and more clinically effective agents (Patani et al pg 3147 first full paragraph). While Patani et al does discuss modifying a lead compound, it does not define the term "lead compound" in the limiting manner that Applicants assert.

Third, while Patani et al discloses a number of bioisosterism modifications, they are not numberless and the skilled artisan would simply pick and choose from among the disclosed potential substitutions to result in the instant compounds. Note, the bioisosteres would all be reasonably expected to have similar functional properties as the compound to be modified, given the teaching is to optimize the effective agent into a more effective agent (Patani et al pg 3147 first full paragraph).

Finally, the compound was not analyzed in relation to formulae 1(A), 1(C), and 1(D) of claim 18, but the elected species does appear to read on formula 1(B). As such, where the species is found to be obvious, the genus encompassing it is likewise obvious.

Claims 23 and 24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al (J. Org. Chem., 1976, 41 (7), 1100-1104) in view of Patani et al (Chem. Rev. 1996, 96, 3147-3176), the combination further in view of Gilbert et al. (Antimicrobial Agents and Chemotherapy, 1986, Vol. 30, No. 2, pp. 201-205).

Applicants assert Sasaki fails to disclose or suggest a composition comprising an effective amount of a compound of claim 21 and Gilbert does not remedy this deficiency.

Examiner disagrees. The rejection of claim 21 over Sasaki et al in view of Patani et al is discussed above, and because Applicants present no arguments why the addition of Gilbert et al would not be obvious for the reasons of record, this rejection is maintained.

Allowed Subject Matter

Claim 20 is allowed for the reasons of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

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/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612